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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,407	09/01/2004	Jocelyne Franchi	26274	8362
20529 7590 NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			EXAMINER COTTON, ABIGAIL MANDA	
			ART UNIT	PAPER NUMBER
			1617	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/01/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/506,407	<b>Applicant(s)</b> FRANCHI ET AL.	
	<b>Examiner</b> Abigail M. Cotton	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2006 and 20 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-84 is/are pending in the application.
- 4a) Of the above claim(s) 36-39, 45-66, 70-73 and 80-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-35, 40-44, 67-69, 74-79 and 84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on September 26, 2006 and November 20, 2006, have been entered.

Claims 31-84 are pending in the application, with claims 36-39, 45-66, 70-73 and 80-83 having been withdrawn as drawn to a non-elected species of invention. Accordingly, claims 31-35, 40-44, 67-69, 74-79 and 84 are being examined on the merits herein.

The objection to claim 31 for a grammatical error is being withdrawn in view of Applicant's amendment to the claim. Also, the rejection of claims 31-35, 41-44 and 84 under 35 U.S.C. 112, first paragraph, as having impermissible new matter, is being withdrawn in view of Applicant's amendment to claim 31.

Applicant's arguments regarding the rejections of the composition claims 67-69 and 74-79 have been fully considered but they are not persuasive. However,

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Applicant's arguments regarding the rejection of method claims 31-35, 40-44 and 84 having been fully considered and have been found persuasive in view of Applicant's amendments to the claims. In particular, it is considered that the combination of Jackson et al, Bombardelli et al. and Fiaschetti et al. would not have provided sufficient motivation to one of ordinary skill in the art to apply the composition containing phytosphingosine to "the part or parts of the body presenting subcutaneous fat," as recited in the amended claim.

The claims are being rejected as follows.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67, 69 and 74-76 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Jackson et al. also does not specifically teach providing a composition with a lipolytic agent, as recited in claim 67. However, Jackson et al. does teach that further cosmetic adjuvants can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Bombardelli et al. teaches a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) in topical formulations (see abstract, in particular.) Bombardelli et al. teaches that the ingredient can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ingredients including the adenylate cyclase stimulator of Bombardelli et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and

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teaches the composition can have other adjuvants, and Bombardelli et al. teaches that ingredients including an adenylate cyclase stimulator act to improve skin aging. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the adenylate cyclase stimulator-containing ingredients of Bombardelli et al. in the wrinkle-treating composition of Jackson et al, with the expectation of providing a composition that treats signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, claim 67 is considered to be obvious over the references.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 69, Jackson et al. teaches that the composition for topical application to the skin can comprise from 0.0001 to 10% by weight of one or more ceramide pathway intermediates such as phytosphingosine, as discussed above, and thus teaches an amount that meets and/or overlaps with the amount recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired properties, such as desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 74, Bombardelli et al. teaches providing an adenylate cyclase stimulator (activating agent), as discussed for claim 67 above. Regarding claim 75, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 76, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize

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the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired sin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, and as applied to claims 67, 69 and 74-76 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Jackson et al and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, to provide an antiaging effect, and also teach that the same parts of the body in need of an anti-aging effect can be those in need of a slimming effect. Jackson et al. and Bombardelli et al. also teach that the composition can comprise an adenylate cyclase inhibitor. Jackson et al. furthermore teaches that the composition can be provided with water as a vehicle (see column 6, lines 15-20, in particular.)



Jackson et al. and Bombardelli et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 68.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in the water-containing vehicle of Jackson et al.

Claim 77 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, as applied to claims 67, 69 and 74-76 above, and further in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. and Bombardelli et al. are applied as discussed for claims 67, 69 and 74-76 above, and teach a composition comprising phytosphingosine and an

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adenylate cyclase stimulator, and a method for applying the composition to the skin.

Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Jackson et al. and Bombardelli et al. do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claim 77.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Jackson et al. and Bombardelli et al, because Jackson et al. and Bombardelli et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition and/or method of Jackson et al. and Bombardelli et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition.

Accordingly, claim 77 is obvious over the teachings of Jackson et al, Bombardelli et al. and Andre et al.

Claims 67, 69, 74 and 78-79 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,578,641 to Jackson et al. issued November 26, 1996 in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Jackson et al. is applied as discussed above, and teaches a method for application to the skin of a formulation comprising phytosphingosine. Jackson et al. further teaches that the composition can be used in the treatment of skin to reduce or delay the development of wrinkles associated with advancing age or with sun-induced aging (see column 2, lines 10-20, in particular.) Jackson et al. also teaches that further cosmetic adjuncts can be provided in the composition (see column 11, line 30 through column 1, line 15, in particular.)

Jackson et al. does not specifically teach providing a composition with a lipolytic agent as recited in claims 67, 69 and 74-79.

Andre et al. teaches that an extract of Tephrosia purpurea provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extract can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extract of Andre et al. in the composition of Jackson et al, because Jackson et al. teaches applying a composition to reduce wrinkles associated with skin aging, and teaches the composition can have other adjuvants, and Andre et al. teaches that an extract that acts as an adenylate cyclase has anti-aging effects in cosmetic compositions. Thus, one of ordinary skill in the art would have been motivated to provide an adjuvant comprising the extract of Andre et al. in the wrinkle-treating composition of Jackson et al. and applying to skin, with the expectation of providing a composition that treats aging of skin such as wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

Regarding the composition of claim 67, it is noted that Jackson et al. teaches a composition for reducing wrinkles associated with ageing, whereas Andre et al. teaches that a composition with an extract that is an adenylate cyclase enzyme stimulator (activating agent) can provide anti-aging effects. Jackson et al. also teaches that the composition can comprise a cosmetically acceptable vehicle (see column 5, lines 60-68, in particular), as recited in the claim. Accordingly, it is considered that one of ordinary

skill in the art at the time the invention was made would have found it obvious to provide the adenylate cyclase activating extract of Andre et al. in the wrinkle-treating composition of Jackson et al., with the expectation of providing a composition that treats aging of skin such as skin wrinkles and has anti-aging effects. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.) Accordingly, the composition of claim 67 is also obvious over Jackson et al. and Andre et al.

It is respectfully pointed out that a recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the cosmetic composition is "notably intended for reducing subcutaneous excess fat," is not afforded patentable weight.

Regarding claim 74, Andre et al. teaches that the extract is an adenylate cyclase enzyme activator.

Regarding claim 69, Jackson et al. teaches a cosmetic composition comprising 0.1% phytosphingosine (see Example 1, in particular), and thus teaches providing the weight percentage recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al, to provide a composition having desired skin treatment properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 78-79, Andre et al. teaches that the extract can be from *Tephrosia purpurea*, and also teaches that the extract can be provided in a topical composition in an amount between 0.01 to 5% by weight (see column 1, lines 45-55 and column 2, lines 20-25, in particular), which meets the range limitation recited in claim 79. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of extract provided in the composition, according to the guidance provided by Andre et al, to provide a composition having desired treatment properties. It is noted that "[W]here

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the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 31-32, 34-35, 40-42 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996.

Bombardelli et al. teaches the topical application of a composition comprising esculoside in combination with an adenylate cyclase stimulator (lipolytic agent) (see abstract, in particular.) Bombardelli et al. teaches that the composition is topically applied for treatment of cellulitis or unesthetisms connected with a deposit of superfluous fat (see abstract in particular.) Thus, it is considered that Bombardelli et al. teaches a method of application of a composition on the part or parts of the body presenting subcutaneous fat, as recited in claims 31 and 32, and also teaches the composition having a lipolytic agent that is an adenylate cyclase enzyme activating agent, as in claims 35 and 40. Bombardelli et al. also teaches that the composition can act to improve skin early aging, particularly face and neck skin (see column 3, lines 1-12, in particular.)

Bombardelli et al. does not specifically teach providing a slimming effective amount of a phytosphingosine compound, as recited in claim 31.

Jackson et al. teaches a composition for topical application to the skin comprising from 0.0001 to 10% by weight of one or more ceramide pathway intermediates (see abstract, in particular.) Jackson et al. teaches that the composition can be applied to human skin for the eradication or reversal of skin aging, removal of rough or dry skin and improving the loss of elasticity and flexibility of skin, among others (see column 2, lines 50-60, in particular.) Jackson teaches that a preferred ceramide pathway intermediate is phytosphingosine (see column 4, lines 14-20, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine of Jackson et al. in the cellulitis and unesthetism treatment composition and method of Bombardelli et al, because Bombardelli et al. teaches treating cellulites and unesthetisms, such as those associated with skin aging, via topical application of the compositions, whereas Jackson et al. teaches that ceramide pathway intermediates such as phytosphingosine can be topically applied to reduce wrinkles associated with skin aging. Thus, one of ordinary skill in the art would have been motivated to provide the skin-aging and wrinkle treating phytosphingosine ingredient of Jackson et al, in the cellulites and skin aging unesthetism treating composition and method of Bombardelli et al, with the expectation of providing a composition and method that treats skin unesthetisms such as cellulitis and other signs of the early aging of skin such as skin wrinkles. Note it is considered that "[I]t is prima facie obvious to combine two compositions each of which is taught by



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the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980.)

It is furthermore noted that the 0.0001 to 10% by weight amount of ceramide pathway intermediate taught by Jackson et al. is considered to meet and/or overlap with the "slimming effective amount" as recited in claims 31 and 34, and an amount that can stimulate the synthesis of leptin by adipocytes, as in claim 84. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of phytosphingosine provided in the composition, according to the guidance provided by Jackson et al. and Bombardelli et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) Accordingly, claim 31 is considered to be obvious over the teachings of Bombardelli et al. and Jackson et al.

Regarding claim 41, Bombardelli et al. teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.) Regarding claim 42, Bombardelli et al. teaches that the adenylate cyclase stimulator can comprise from about 0.1 to 1% of the composition (see column 1, lines 40-65, in particular), and thus

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teaches an amount that meets the limitations of the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of adenylate cyclase stimulator provided in the composition, according to the guidance provided by Bombardelli et al. to provide a composition having desired skin treatment effects. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, and further in view of WO 00/53568 to Streekstra et al, published September 14, 2000.

Bombardelli et al. and Jackson et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenylate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Bombardelli et al. furthermore teaches that the composition can be provided with a pharmaceutically acceptable carrier and exemplifies compositions containing water as a carrier (see column 1, lines 58-62, and Examples I-III and V, in particular.)

Bombardelli et al. and Jackson et al. do not specifically teach providing phytosphingosine in the form of phytosphingosine hydrochloride, as recited in claim 33.

Streekstra et al. teaches that forming the salt of sphingoid bases, such as the hydrochloric acid salt phytosphingosine, provides a sphingoid compound having better solubility in topical formulations containing water than their free base counterparts (see page 2, lines 1-35, and page 3, lines 15-17, and Example 3, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the phytosphingosine hydrochloride of Streekstra et al. in the phytosphingosine-containing composition of Bombardelli et al. and Jackson et al, with the expectation of providing a phytosphingosine form having improved solubility in a water-containing vehicle of Bombardelli et al. and Jackson et al.

Claims 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,679,358 to Bombardelli et al, issued October 21, 1997, in view of U.S. Patent No. 5,578,641 to Jackson et al, issued November 26, 1996, as applied to claims 31-32, 34-35, 40-42 and 84 above, in view of U.S. Patent No. 5,709,864 to Andre et al, issued January 20, 1998.

Bombardelli et al. and Jackson et al. are applied as discussed for claims 31-32, 34-35, 40-42 and 84 above, and teach applying a composition to skin comprising a ceramide pathway intermediate, such as phytosphingosine, and an adenylate cyclase inhibitor, to treat cellulites and other unesthetisms associated with aging, such a skin wrinkles. Bombardelli et al. furthermore teaches that the adenylate cyclase stimulator can be forskolin (see abstract, in particular.)

Bombardelli et al. and Jackson et al. and do not specifically teach providing an adenylate cyclase stimulator that is an extract of *Coleus forskohlii* or *Plectranthus barbatus*, as recited in claim 43, or that is an extract of the plant *Tephrosia purpurea*, as recited in claim 44.

Andre et al. teaches that an extract of *Coleus forskohlii* contains forskoline (forskolin) and is known for its activity in stimulating adenylate cyclase (see column 5, lines 60-68, in particular.) Andre et al. also teaches that an extract of *Tephrosia purpurea* provides powerful stimulation activity of the enzyme adenylate cyclase (lipolytic agent) (see column 1, lines 30-45, in particular.) Andre et al. teaches that the extracts can be provided in a cosmetic composition to provide anti-aging effects (see abstract, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was known would have found it obvious to provide the *Coleus forskohlii* extract or *Tephrosia*

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purpurea extracts of Andre et al. in the phytosphingosine and adenylate cyclase stimulator composition and method of Bombardelli et al. and Jackson et al, because Bombardelli et al. and Jackson et al. teach that an adenylate cyclase stimulator such as forskolin can be provided, and Andre et al. teaches that an extract of *Coleus forskohlii* provides the forskolin adenylate cyclase stimulator, and that *Tephrosia purpurea* extract also provides an adenylate cyclase activating agent. Thus, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the extracts of Andre et al. in the composition and/or method of Bombardelli et al. and Jackson et al, with the expectation of providing a suitable forskolin containing adenylate cyclase stimulator in the composition and method. Accordingly, claims 43-44 are obvious over the teachings of Bombardelli et al, Jackson et al, and Andre et al.

### ***Response to Arguments***

Applicant's arguments with respect to the rejections of claims 31-35, 40-44 and 84 have been considered but are moot in view of the new grounds of rejection.

Applicant's arguments regarding the rejections of claims 67-69 and 74-79 have been fully considered but they are not persuasive.

In particular, Applicants argue that Jackson et al. and Bombardelli et al. do not teach a composition that is "notably intended for reducing subcutaneous fat", as recited

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in claim 67. The Examiner notes that, as discussed above, an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963.) Thus the intended use recited in claim 67, namely that the composition is intended to reduce subcutaneous fat, is not afforded patentable weight.

Applicants also argue that the combination of Jackson et al. and Bombardelli et al. is not obvious, because they assert that Jackson et al. "teaches an increase in lipids in the dermis," whereas Bombardelli et al. teach a "reduction of fat in the dermis," and thus one of ordinary skill in the art would not have found it obvious to combine them because, according to Applicants, they "act by completely different mechanisms to obtain opposite results" (see second full paragraph of page 14 of Remarks submitted on November 20, 2006, in particular.) The Examiner respectfully disagrees. Jackson et al. teaches that the ceramide pathway intermediates (e.g. phytosphingosine) improves the skin health by promoting synthesis of ceramides in the epidermis to improve the water barrier properties thereof (see column 1, lines 45-63, in particular.) In contrast, Bombardelli et al. teaches that the composition seek to improve conditions, such as cellulitis and other unesthetisms, including skin aging, by improving peripheral

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microcirculation and blood flow to skin areas (see column 1, lines 25-40, in particular.)

Thus, contrary to Applicants implications, Bombardelli et al. does not teach that the cellulite treatment is achieved by reducing the very same epidermal ceramides that Jackson et al. seeks to promote, and indeed is silent on the issue of reducing epidermal ceramides in general, which are distinct from the subcutaneous fats that are the source of cellulite, and instead teaches that treatment is achieved by improving the microcirculation and blood flow to the region. Accordingly, one of ordinary skill in the art would not have any reason to doubt that the skin and aesthetic improvement mechanism of Jackson et al. and Bombardelli et al. could be used together, and thus would not have been taught away from the combination by the teachings of the references.

### ***Conclusion***

No claims are allowed.

The prior art made of record and not relied upon that is considered pertinent to applicant's disclosure is recorded on the accompanying PTO-892 form.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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AMC

  
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